NFPA
The Food Safety People

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

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USDA/FSIS
Room 102, Cotton Annex
300 12th Street, SW
Washington, DC 20250-3700

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97-013P
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[Docket No. 97–013P] **Performance Standards for the Production of Processed Meat and Poultry Products; 66 *Federal Register* 12590; February 27, 2001**

Dear Ms. Moore:

NFPA is the voice of the $460 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the Association's U.S. and international members. NFPA's members produce processed and packaged fruit, vegetable, and grain products; meat, poultry, and seafood products; snacks, drinks, and juices; or provide supplies and services to food manufacturers.

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GENERAL COMMENTS

The proposed rule setting performance standards for the production of processed meat and poultry products is massive in scope and will have a very significant impact on our members who manufacture a major portion of the ready-to-eat (RTE) products in the marketplace. NFPA notes that in addition to extending lethality and stabilization performance standards to all other cooked RTE products, this proposal contains performance standards for canned products. These proposed standards have the potential to reduce the level of public health protection provided by the current regulatory requirements for thermally processed, commercially sterile meat and poultry products. The canning regulations promulgated by FDA more than 25 years ago and more recently adopted by FSIS upon our petition have represented an outstanding example of industry/agency cooperative effort to successfully

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address a recognized food safety problem. We also note that, as proposed, the *Listeria* testing requirements may also have a negative impact on public health to the extent that they act as a disincentive to aggressive testing programs needed to minimize contamination of RTE products in which *Listeria monocytogenes* can grow.

We believe that many of the provisions outlined in this proposal will not result in a positive impact on public health and are likely to impose significant economic expenditures for the meat and poultry industry. NFPA and the American Meat Institute (AMI) conducted a survey of member companies to gather industry data on the impact of this proposal. The results of this survey have been presented to FSIS and are attached to these comments. We strongly urge FSIS to carefully review all the information provided in the survey summary as it reflects current industry data based on the proposal as written.

The Agency has attempted to cover a variety of issues within a single rulemaking effort. We believe that three separate and distinct matters are melded together to the detriment of the overall docket. We strongly encourage the Agency to address as separate issues 1) lethality and cooling performance standards for cooked RTE products other than thermally processed; 2) *Listeria* testing in plants producing RTE products; and 3) thermally processed, commercially sterile products. The lethality and stabilization performance standards should be re-proposed after revisions based on submitted comments. We strongly urge the Agency to withdraw its proposal to eliminate the existing regulations for canned food products, as this is unnecessary and could have a negative impact on public health. We also urge the Agency to carefully reconsider the approach taken with respect to *Listeria* testing. The Agency should evaluate the impact that recent actions, including industry utilization of voluntary testing provisions in the revised microbiological testing directive (FSIS Directive 10,240.2), have had on *L. monocytogenes* control. If, after such evaluation and careful review of the submitted comments, the Agency determines the need to mandate such testing, we urge the Agency to significantly revise its approach, taking into account the results of the FDA/FSIS *L. monocytogenes* risk assessment, and re-publish this as a proposed rule.

The true test of the appropriateness of this proposed rule is whether or not its provisions will ultimately enhance food safety; some proposed provisions appear to present a significant burden with little or no likelihood of either enhancing food safety or providing a positive impact on any public health endpoint; and indeed, several provisions have the potential for lessening public health protections. In brief, certain provisions of the proposed rule have a greater potential "to do harm" than to enhance public health. And as we all know the first precept for advancing any public health measure – including those designed to advance food safety – is "to do no harm."

Highlights from Specific Comments

The proposed requirements for *Listeria* testing do not reflect the findings of the interagency *Listeria monocytogenes* Risk Assessment. Readily identifiable differences in public health risk

presented by various categories of products have not been considered in this proposal. For example, the requirements for frozen entrees, which do not support the growth of *L. monocytogenes*, are no different from those for pâté, which had the highest calculated relative risk on a "per serving" basis. In this regard, the Agency fails to adhere to the strategy upon which it based the Pathogen Reduction/HACCP final rule, namely to focus "...FSIS inspection on the most significant hazards and controls." Moreover, we believe that this approach will be less effective in meeting the directive by the President in May 2000 to take aggressive steps to reduce *L. monocytogenes*-related disease by 50% by 2005. We believe that a regulatory scheme that encourages firms to implement environmental testing designed to detect and eliminate *L. monocytogenes* will be more effective than the proposed mandatory minimum testing requirements.

Validation data expectations should be practical and realistic. The proposed rule does not provide adequate discussion of the Agency's expectations, nor were they revealed during the Agency's public meeting on this subject.

The Agency's stated intent to provide increased flexibility to processors is unlikely to be realized under the proposed provisions.

The compounded conservative assumptions utilized by the Agency have yielded performance standards that would be unnecessarily difficult to achieve and are unrealistic in actual practice.

The costs for hold and test programs for *Listeria* will be very significant for industry; in fact, they are likely to discourage industry testing. Our estimates (detailed below in our comments) indicate that costs of such programs for the large plants alone are likely to exceed $100 million annually.

There is no public health or food safety basis for the proposed conversion of canning regulations into performance standards; the proposed changes would not enhance food safety; in fact they could have a detrimental effect on a regulation that has proven to be exceptionally effective in minimizing food safety problems.

SPECIFIC COMMENTS

The comments below are divided into three primary sections: lethality and stabilization performance standards; testing for *Listeria* spp.; and canning performance standards. Comments are also provided on proposed changes in labeling requirements for RTE products, including canned food products.

Lethality and Stabilization Performance Standards for Cooked RTE Products

Definitions

We believe that FSIS and FDA should be consistent in their definition of "ready-to-eat food" and should use the *Food Code* definition of that term: "'Ready-to-eat food' means food that is in a form that is edible without washing, cooking, or additional preparation by the food establishment or the consumer and that is reasonably expected to be consumed in that form." Based on this definition, foods that would subsequently be heated would not be considered RTE, at least with regard to *Listeria* testing. We believe that FSIS should be consistent with this policy, which is followed by FDA, because it more accurately reflects consumer expectations for RTE products.

We question the advisability of codifying specific numbers in the definition of "worst-case product." FSIS proposes to codify the definition of worst-case product based on dated baseline studies conducted by the Agency from 1992-1995. This fact, combined with the Agency's use of the worst case for each assumption made in the calculation, has resulted in hypothetical worst-case product conditions that are highly unlikely, if not impossible, to ever occur. Indeed, we contend that meat with 10^6 *Salmonella* would be so obviously unwholesome that it would not be used by processors nor would it be permitted for use in USDA-inspected food production operations. Moreover, the Agency has touted the fact that *Salmonella* prevalence is decreasing as a result of industry-wide implementation of the HACCP/Pathogen Reduction rule. Assuming that *Salmonella* prevalence will decline further over time, and that reduction in prevalence also results in a reduction in the number of *Salmonella* present, the definition of "worst-case" product will unnecessarily become more and more conservative and/or the Agency will be required to amend it periodically.

Furthermore, if the specific number of *Salmonella* in worst-case product (6.7 logs/143 g in raw poultry; 6.2 logs/143 g in raw meat) is codified, there is no flexibility to derive an alternative lethality process as noted below. We believe this definition should be eliminated or redefined to remove these numbers.

Lethality Performance Standard

It is inappropriate to apply the lethality performance standard to products made from meat and poultry ingredients that have previously been processed in an FSIS-inspected establishment. We agree with the selection of *Salmonella* as a reference organism for lethality performance standards for the reasons the Agency cited. However, the proposed requirements are confusing and appear to be excessively conservative in consideration of industry practices. The most notable concern is that many processed food products use previously cooked ingredients from inspected establishments in their products without further cooking. The proposed regulations provide exemption only to thermally processed,

commercially sterile products. We respectfully suggest that the Agency intended these lethality performance standards to apply only to those establishments that are processing **raw** meat and poultry products into further-processed products, and not to the vast numbers of prepared products that are made using USDA-inspected fully cooked ingredients. Establishments that purchase and use fully cooked meat and poultry ingredients should also be exempt from the lethality performance standards, as the performance standards were met prior to release from the original USDA-inspected processing establishment. In any event, applying the proposed worst-case product assumptions to previously fully cooked meat or poultry ingredients is clearly inappropriate.

As written, the wording of the proposed rule does not appear to allow for the flexibility promoted by the Agency in preamble discussion. We agree with the need to allow alternative lethalities, but question whether the process defined by the Agency is workable. The proposed rule states that lethality processes must be validated to achieve specified low probabilities that *Salmonella* remain in finished product "assuming the incoming product is worse [sic] case." The Agency may have intended the wording of this provision to indicate solely that it used worst-case product in calculating its probabilities, but it could readily be interpreted as requiring that a processor who is attempting to establish an alternative process must assume that his starting product is worst-case product. Since worst-case product is codified as having a certain number of organisms present, how can any firm develop an alternative lethality based upon their documented ability to start with fewer organisms (as discussed in the preamble), when required to assume worst-case product?

In comments made regarding proposed performance standards for the production of certain meat and poultry products [Docket No. 95-033P], which have since been finalized, NFPA recommended that food safety objectives, rather than performance standards, should be codified. There is a food safety objective (FSO) that underlies any performance standard. For example, producing a product that presents a negligible risk from *Salmonella* and other vegetative pathogens is the food safety objective that underlies FSIS' proposed lethality performance standard. In its lethality performance standard, FSIS has quantified this food safety objective by specifying the probabilities of surviving *Salmonella* that present a negligible risk to consumers for a cooked meat or poultry product. This should theoretically allow processors flexibility to design processes to meet the FSO. In practice, it may be difficult to develop an alternative process if the Agency expects industry to adhere to the same assumptions and statistical procedures outlined in its technical paper on the lethality and stabilization performance standards. Moreover, there is no clear guidance on how much testing a company would need to conduct to establish that its raw material has initial numbers different from the Agency's baseline data.

We believe that the proposed worst-case product numbers are unrealistic based on available data and inconsistent with decreasing trends in the prevalence of *Salmonella* on raw meat and poultry. The hypothetical worst-case product numbers were based on overly-conservative statistical derivations that are not likely to represent actual situations. The Agency's technical paper on the lethality and stabilization performance standards notes that in a theoretical population of ground poultry samples, the high value of 2300 MPN/g could range, with 99% confidence, from 0.00086% to 1.279%. This would indicate that approximately 1% of 25-g portions of ground poultry could have MPN values of 2300/g. This number is then statistically transformed to 6.7 logs using a 97.5% upper confidence limit, assuming 30% recovery, and 143 g of raw product. However, according to the technical paper, 54% of the samples tested were negative, only 76 of 131 samples could be quantified, and the geometric mean of MPN-positive samples was 1.26 MPN/g (range 1.17-1.35). The probability of >4 surviving salmonellae in finished product of 0.0174% (for raw product containing 6.7 logs and given a 7-log lethality treatment) is once every 5,747 times. However, given that only 1% of ground poultry samples (or even as low as 0.0009%) hypothetically contain 2300 MPN/g, that the highest count for beef was 240 MPN/ cm^2, that most samples have much lower numbers, and that, according to FSIS, the prevalence of *Salmonella* on raw product is decreasing, we strongly believe the lethality performance standards are too conservative.

Based on the Agency's baseline data, there was a maximum MPN/g of 2300 in samples from raw ground chicken and 240 MPN/ cm^2 in beef from cows and bulls. It should be noted that these data obtained in slaughter plants are based on the maximum level of surface contamination. Obviously, the surfaces of products, which are cooked to achieve a specified internal lethality value, are subjected to much, much higher lethality.

As noted above under the "worst-case product" discussion, the starting assumption about the number of organisms present in meat or poultry ingredients artificially raises not only the performance standard itself (6.5- or 7-log reduction), but also raises the level of lethality required to meet the probability of surviving organisms which must be met by establishments who might wish to utilize the proposed option for alternative lethality. In either case, the result is that firms will be required to provide their products with a more severe heat treatment than we believe is necessary based on science. It should be noted that the worst-case numbers used to establish a requirement for a 6.5- or 7-log reduction performance standard were based on hypothetical contamination levels in 143 g of raw product. Generally a performance standard of X-log lethality assumes that a process would deliver this lethality to the cold spot of the product. Clearly the worst-case numbers of organisms are not located in a single spot, so additional conservatism is inherent in delivery of the process. Although some processors might have the technical expertise to calculate a process based on integrated lethality throughout the product, clearly this is beyond the capability of most processors. It should also be recognized that

processes are established to deliver heat treatments that account for process variability based on the individual capability for each processing line. If a 6.7-log treatment is required by regulation, processors are likely to use processes that deliver a higher lethality to assure compliance. This extra measure of heat combined with the overly conservative performance standards will likely reduce product quality due to overcooking, especially for beef products, without measurable improvement in product safety. As a result, processors may be driven to consider the manufacture of partially cooked products rather than fully cooked products in order to meet consumer expectations for product quality. We suggest that this outcome, while permissible under the regulations and perhaps necessary in order to market products that consumers desire, would be counter to the Agency's intent to improve food safety.

Given the fact that the worst-case numbers appear to be excessive, NFPA believes that sound science supports a 5D reduction in *Salmonella* and provides an adequate level of safety for cooked meat and poultry products. Further rationale for this was provided in our comments submitted on September 9, 1996 in response to Docket No. 95-033P, where we concluded the following:

> A 5-D reduction of *Salmonella* for all meat and poultry products is adequate because:
> - the numbers of pathogens on raw meat and poultry are low;
> - a 5-D process incorporates a 2-log safety factor;
> - it would also inactivate sufficient numbers of other vegetative pathogens such as *Campylobacter, Listeria monocytogenes*, and *Escherichia coli* O157:H7.

A history of successful performance is a factor that should be considered in setting the level of conservatism appropriate for establishing lethality performance standards. As a general rule, a higher threshold of conservatism is more appropriate when faced with the unknown rather than when a documented history of successful production is available. It is not uncommon for a firm processing a new product or inaugurating a new processing system to take a more conservative approach to safety in the face of the unknown. However, once a history of successful operation has been compiled, it frequently will be possible to refine the degree of conservatism necessary for a given level of assurance of product safety. If the performance standards being proposed by the Agency mean increased processing requirements for products that have long been manufactured safely with lesser processes, this seems a clear indicator that the assumptions used to calculate the performance standards are too conservative and should be reevaluated in light of this practical information. We believe this is the case with respect to requiring meat patties to increase from a 5-log to a 6.5-log process for *Salmonella.*

As previously noted, NFPA and AMI surveyed our members regarding the impact of the proposal. Data from the lethality section of the survey found that 80% of the companies responding did in fact have a CCP that would meet the proposed log reductions for *Salmonella.* Sixty-two percent (62%) of those with CCPs that met the requirements had already validated the CCP at an average cost/plant of $3,004. However, 15% of respondents indicated that they did

not have a CCP that meets the requirements, and 37% of those who did have a CCP had not validated it. Plants estimated an average of more than $20,000 to validate the CCP. When questioned about the section of the draft compliance document on lethality, 72% of respondents reported that it was helpful. Nevertheless, the discrepancy between costs to validate by those who had done so and those who estimated what the costs would be probably indicates a need for clearer guidance on Agency expectations for validation of lethality performance standards.

Stabilization Performance Standard

The requirement to demonstrate stabilization against *C. perfringens* growth in many formulated products would be costly, yet would yield no substantive public health benefit. The Agency is proposing stabilization performance standards for the entire range of RTE products when only a select group of products have historically been associated with *Clostridium perfringens* foodborne illness (e.g., roast meats and poultry and gravy) primarily in foodservice settings. Broad implementation of stabilization performance standards for *C. perfringens* and the associated validation studies to document compliance with the *C. perfringens* stabilization performance standard would be inappropriate for many processed foods. For example, *C. perfringens* is not reasonably likely to present a hazard in frozen products because spores cannot germinate and vegetative cells, which are required to produce illness, are very sensitive to freezing.

Conservative assumptions in setting the proposed stabilization performance standards are likely to create undue difficulty for industry, despite the absence of any indication of a food safety problem. Even with industry practices that have performed successfully for decades, it may be very difficult to readily validate existing procedures. If desired scientific supporting data are not readily available, they cannot be generated overnight. We would argue there is no valid scientific reason to devote significant resources to such an effort.

The proposed performance standard for zero growth of *Clostridium botulinum* is both unnecessary and unmeasurable. FSIS is proposing that processing must prevent the multiplication of *C. botulinum* and limit growth of *C. perfringens* to no more than one log. While in principle there should be no tolerance for growth and toxin production by *C. botulinum*, practically speaking we do not measure growth of the organism *per se* but toxin production. *C. botulinum* is unlikely to be present in meat and poultry, and when present its numbers are very low (ranging from <0.1 spore/kg to 7 spores/kg; summarized in Tompkin, R.B., 1980, Botulism from meat and poultry products – a historical perspective. *Food Technology* 34(5): 229-36, 257 and Hauschild, A.H.W., 1989, *Clostridium botulinum*. In *Foodborne Bacterial Pathogens*, M.P. Doyle, ed., Marcel Dekker). We believe that limiting growth of *C. perfringens* will effectively limit growth of *C. botulinum* in commercial food processing establishments. While non-proteolytic strains of *C. botulinum* may grow more rapidly than *C. perfringens* at cooler temps (e.g. 19°C), it takes days to grow at that temperature. In fact, *C. botulinum* generally

demonstrates a prolonged lag phase of several days in foods, even when inoculated at levels much higher than might reasonably be expected in meat (ICMSF, 1996, Microorganisms in Foods 5: Microbiological Characteristics of Food Pathogens, Blackie Academic). Such lengthy cooling procedures are not known to exist in inspected meat and poultry establishments. There have been no cases of botulism due to improper chilling or to an extended cooling procedure for meat and poultry products made in USDA-inspected establishments. Moreover, it is not clear to us how one would attempt to measure zero growth of this organism when enumeration methods are cumbersome and yield highly variable results.

FSIS is proposing the same stabilization performance standard for all meat and poultry products. A review of the baseline data on *C. perfringens* indicates that beef carcasses have much lower levels of contamination (no *C. perfringens* were detected in 91.7-97.4% of the samples, and 98-99% of the samples had < 100/g; 53.3% of ground beef samples were contaminated, but 99.5 % had ≤ 1000/g). Although poultry samples were more frequently positive (29% for turkey, 43% for broilers), over 99% had < 100/ml of carcass rinse. Except for ground beef, contamination prevalence and levels for ground meat and poultry were similar to those for carcasses. The estimates for *C. perfringens* in raw ground products were weighted, "taking into account the probability of selection, the volume of the establishments and the non-response." It is not possible to assess the impact of this on the calculations.

It is important to note that the baseline studies enumerated presumptive *C. perfringens*; there was no confirmation of *C. perfringens*-like colonies from plates (see FSIS MLG, Chapter 13). Thus the counts are likely to include other species of Clostridia. Because the procedure did not incorporate a step to inactivate vegetative cells, the baseline numbers cannot be used as an estimate of the level of *C. perfringens* spores, which are the concern with respect to growth during cooling (stabilization) of meat and poultry products (since vegetative cells would be destroyed by cooking, leaving only spores). Thus the "worst-case" calculation of 10^4/g used as the basis for setting the performance standard is not valid.

Moreover, these numbers of *C. perfringens*, even if they were valid for raw products, would not reflect levels of *C. perfringens* in cooked products. Spores of different strains of *C. perfringens* may vary widely in their heat resistance, and in most environments heat sensitive strains outnumber heat resistant strains. For many of the products, heat treatments may be sufficient to reduce the number of spores. Clearly the worst case of 10^4/g does not reflect the level of *C. perfringens* spores in most meat and poultry products. Industry data on products analyzed for cooling deviations previously submitted to the Agency from one meat processor demonstrated anaerobic and/or *C. perfringens* counts were low (<100/g, and usually <10/g). Data on levels of *C. perfringens* in raw product obtained by an industry survey related to these proposed performance standards (attached) in general support these numbers.

C. perfringens must grow to 10^5-10^6/g to cause illness. Given that low levels of spores are generally present in meat and poultry products and that industry practices do not result in levels of *C. perfringens* that even approach 10^4/g after cooking, we believe that a stabilization performance standard that restricts multiplication to one log is overly conservative. This proposed performance standard is likely to result in the needless expenditure of time and money to evaluate cooling deviations and to demonstrate that product is not adulterated or, alternatively, in the needless destruction of product that is safe and wholesome. Moreover, the performance standard seemingly has led to the Agency questioning the safety of product manufactured under commercial practices with a long history of safety.

We believe the Agency should reconsider the need for stabilization performance standards, including its existing stabilization performance standards for certain cooked meat and poultry products. They are not required because manufacturers of RTE products are already required by HACCP regulations to assess the potential for cooling to result in a risk to public health. Before proceeding to set any specific requirements for cooling, the Agency should obtain data on levels of clostridial spores both from the literature and from carcass sampling. Then, if the Agency proceeds to set a performance standard for stabilization, we believe that, given the low levels of *C. perfringens* spores in raw product and the number of cells required to cause illness, science supports a standard that allows at least 2- to 3-log growth of *C. perfringens*. Any stabilization performance standard that FSIS might establish should include a provision for an alternative Food Safety Objective of *C. perfringens* of 500-1000 CFU/g in cooled product.

We are unaware of a single instance in which chilling of meat and poultry products in a manufacturing facility according to current practices has resulted in foodborne illness, including illness from *C. perfringens*. To the best of our knowledge, *C. perfringens* outbreaks have been associated with food service establishments, not food processing establishments, and have been the result of inadequate hot holding or gross temperature abuse during improper cooling.

Industry costs for meeting the stabilization performance standards will be substantial. The previously mentioned industry survey found 57% of the companies responding had a CCP in place that meets the proposed requirements for no more than 1-log increase of *C. perfringens* and no increase in *C. botulinum.* Of those that have a CCP in place, only 51% indicated the CCP had been validated. The average cost per plant of the validation process was $5,203. However, estimates to validate a cooling CCP from those who have not done so averaged over $19,000 per plant. As with validation of lethality, there appears to be a need for clearer guidance on Agency expectations for validation. Furthermore, if this rule is finalized, the industry will experience significant costs, in addition to initial validation costs, for needless evaluation of cooling deviations and/or destruction of product solely as a result of the stringency of this requirement.

Maintenance of performance standards over shelf life

The intent of the requirement that processing for RTE products "...must be validated to maintain the lethality (and the stabilization) performance standards throughout product shelf-life ..." is not clear, nor are the means by which a firm would attempt to comply with the requirement. The lethality performance standards essentially require the elimination (reduction to an undetectable level) of *Salmonella*, *E. coli* O157:H7, and other pathogens and toxins that would render an RTE product adulterated. If any of these agents are found in an RTE product at any time, the product is considered adulterated. We do not disagree with this. While there is much discussion of labeling options related to shelf-life, we find no preamble discussion of the requirement to maintain the lethality (or the stabilization) performance standard throughout the shelf-life of the product.

We understand that the intent of this provision may be to provide the Agency with additional authority to take action when post-process contamination of RTE products occurs. Yet the lethality and the stabilization performance standards are met at a point in time during processing operations. For example, once a poultry product has received a heat treatment adequate to provide a 7-log reduction in *Salmonella*, the lethality performance standard has been met. Similarly, once this product is cooled to an appropriate temperature in an appropriate length of time to prevent more than a one-log increase in *C. perfringens*, the stabilization performance standard has been met. Any cross-contamination that might reintroduce *Salmonella* to the product, or any elevation of product temperature once it has left the processing facility such that *C. perfringens* can multiply to undesirable levels is unfortunate, but is a separate matter from achieving these performance standards. If the Agency's intent is to establish new performance standards for post-process contamination (which we do not believe is necessary), then FSIS should be much clearer about this and it should be a separate element of the proposed rule. Moreover, in clarifying the intent of this section, FSIS should also describe its expectations with respect to validation. In order to clarify this provision, we believe it would be most appropriate for the Agency to re-propose this section before finalizing it.

Use-by Date Labeling Issues

In determining not to proceed at this time with a requirement for "use-by" dates on labels of RTE products, FSIS correctly recognized that ".... further information regarding the potential effects of use-by date labeling is needed." For example, as FSIS noted, information is needed on current consumer understanding of use-by date labeling, on the likelihood that consumer practices will change as a result of labeling, and on the effect of changes in consumer behavior on listeriosis cases. Also, data are needed to assess the reduction in risk that would occur from this change and on how use-by date labeling would affect the production and shipment patterns of labeled ready-to-eat meat and poultry products.

We note FSIS plans, in conjunction with FDA, to present the issue of "use-by date labeling issues to the National Advisory Committee on Microbiological Criteria for Foods for its review. We concur that no action should be taken on "use by" date labeling until the NACMCF review has been completed and this additional information is available.

While we recognize that a product that does not support growth of *L. monocytogenes* does not pose the same risk as one that supports growth, currently, any RTE product containing *L. monocytogenes* is adulterated. It is not clear what FSIS' expectations are with respect to a use-by date, since even low levels of *L. monocytogenes* are not permissible under current regulatory policy. If the Agency were to establish a regulatory approach that would allow products in which *L. monocytogenes* does not exceed a specified low level during its shelf life, not only could a use-by date be established to help manage the risk from *L. monocytogenes*, but also this would encourage the development and use of new product formulations that will not support growth of the organism. For this reason, we believe such a policy that establishes a specified low level would benefit public health. Furthermore, we believe that the joint FDA/FSIS *Listeria monocytogenes* risk assessment provides the framework for such a regulatory approach.

Testing for *Listeria* Species

NFPA strongly supports development and use of processing technologies for positive control of pathogens of concern in RTE products. The most effective controls combine the ability to destroy pathogens of concern with the ability to prevent recontamination. In most cases this requires processing technologies that can be utilized on the finished product in its final packaging. Post-packaging pasteurization, irradiation and high pressure processing are promising examples of such technologies. In situations where such technologies can be applied, they offer the very best assurance of product safety and protection of public health. USDA research efforts to help develop these technologies, to help expedite their clearance, if necessary, through the food additive approval process (for irradiation, for example), and to help educate consumers to their substantial food safety benefits are all very worthwhile efforts, which NFPA and its members heartily endorse.

Unfortunately, in their current state, these technologies may not be compatible with many of the RTE foods that American consumers desire or may be cost-prohibitive at this time for smaller processors. Under these circumstances, NFPA strongly supports regulatory acknowledgement of and creation of incentives for interventions that will minimize the potential for growth of pathogens. One area that requires FSIS attention is the expedited approval of food additives. Despite the fact that FDA and FSIS agreed to regulatory changes to eliminate duplication of effort in the food additive approval process, we are aware of promising new additives that have

been approved by FDA, but are not being allowed to fulfill their promise since FSIS approval has not yet been granted.

Products subjected to an in-package lethal step to eliminate *Listeria* should be exempt from both environmental and finished product testing. (The preamble and economic impact discussions indicate that canners are effectively eliminated from the *Listeria* testing requirements; we believe that similar logic would exclude other products that are given a lethal treatment in the package. However, we believe the language in the regulation should be clearer in this regard.) Likewise, products that do not support growth of *Listeria* and are formulated to provide a lethal effect that eliminates *Listeria* also should be exempt from both environmental and finished product testing.

As we have noted on numerous occasions, industry believes the key to protecting public health with respect to listeriosis is to emphasize the need for manufacturers to develop and implement a *Listeria* control program. The essential component of a control program for RTE products not given a listericidal process in the final package is aggressive environmental testing with a disciplined root cause analysis and a corrective action program to address the results of the monitoring program. We believe that such programs are best promoted by a regulatory policy that encourages, rather than discourages, firms to test for, find, and eliminate harborages for this ubiquitous pathogen.

It is critical that the Agency address the findings of the *L. monocytogenes* risk assessment in this rulemaking initiative. We believe the Agency should reconsider its approach and re-propose this section of the rule, taking into account the key findings of the *L. monocytogenes* risk assessment. The risk assessment made clear that not all RTE food products present the same level of risk to the consuming public; consequently, it would be inappropriate and burdensome for the Agency to regulate all RTE products in the same manner.

A primary intent of the *L. monocytogenes* risk assessment was to identify those products for which additional industry and regulatory measures might yield the greatest public health benefit. Yet this proposal mandates a "one-size fits all" requirement for all RTE products for which *L. monocytogenes* is not addressed in the HACCP plan. The results of the risk assessment clearly show that those products that do not permit the growth of *L. monocytogenes* under intended conditions of handling and storage do not present the level of risk associated with products that do.

We suggest the following strategy:

Based on the findings of the *L. monocytogenes* risk assessment, we believe that ready-to-eat products that inhibit growth of *L. monocytogenes* through formulation (e.g., foods containing inhibitory compounds) or means of distribution (e.g., frozen foods) do not scientifically warrant the same criteria applied to those that do support growth. Also based on the risk assessment

findings, we believe that products that are intended to be heated or cooked present less risk than those that are intended to be and are commonly consumed without further preparation. The former need not be held to the same stringent requirements as the latter to achieve the same level of safety.

Regardless of whether products support growth or not or will be heated or not, we believe that manufacturers should implement programs (such as a prerequisite program) to minimize contamination by *L. monocytogenes*. It would also be appropriate to have an environmental monitoring program to assess the potential for recontamination of product. However, the actions taken in response to a positive *Listeria* spp. on a food contact surface could be less stringent for those types of products that present less of a risk because of factors that minimize growth or reduce the level of contamination. For example, with products in which *L. monocytogenes* cannot grow, actions in response to detection of *Listeria* spp. on a food contact surface might focus on enhanced sanitation and retesting of the surface without the need for product testing, whereas, for products in which *L. monocytogenes* can grow, repeated positives (e.g., 2-3 consecutive positives) on a food contact surface could indicate a likely harborage and would usually trigger product testing. In frozen products intended to be cooked before consumption, where growth is inhibited by freezing and low numbers of organisms that might be present would be destroyed by cooking, we see no benefit to product testing.

Likewise, we believe that the Agency should recognize that *Listeria* testing for cooked products that are intended for further processing, such as ingredients in canned products, is an inefficient and ineffective utilization of limited Agency resources for microbiological testing. In this same light, we believe cooked products that are intended and labeled for further processing as a component of fully cooked RTE foods or which are destined for use in not-ready-to-eat (NRTE) foods, should not be subject to the proposed testing requirement.

We believe that FSIS should focus its monitoring activities on products in which the organism can grow. We also believe that the Agency should devise a new strategy under which the finding of low levels of *L. monocytogenes* in products that will not permit growth to high numbers will be dealt with in a different manner than for other products. This strategy would be similar to that in other countries such as Canada. We are confident that such a strategy will have a very positive effect on public health, by giving manufacturers an incentive to reformulate or otherwise develop products that will not support the growth of *L. monocytogenes*.

The first sentence of proposed §430.4 (a) is not clearly written and is subject to more than one interpretation. Preamble discussion suggests that a firm must identify *L. monocytogenes* as a hazard reasonably likely to occur and establish a HACCP critical control point (CCP) for its control in order not to have to comply with the testing requirement. However, this provision could be interpreted as meaning that if a firm did not identify *L. monocytogenes* as a hazard reasonably likely to occur, but did establish controls (even outside of HACCP, such as in SSOPs,

or in some other prerequisite program), then environmental testing for *L. monocytogenes* per the proposed regulation would not be required.

The Agency continues to conclude that the mere presence of a pathogenic organism constitutes a food safety hazard when in fact presence without growth does not necessarily constitute a public health concern. FSIS appears to recognize this reality in its risk management of *C. botulinum* and *C. perfringens* as the proposed regulation provides for the presence of these pathogens in products, as long as growth is controlled. The results of the FDA/FSIS risk assessment suggest that controlling growth of *L. monocytogenes* can significantly reduce risk. While ice cream is not regulated by FSIS, it provides a useful case to examine on a scientific basis. Ice cream is truly a ready-to-eat product in that it is consumed directly in the form in which it is sold to the public. Recalls of ice cream have occurred because of the presence of *L. monocytogenes*, yet ice cream is not known to have ever caused an outbreak of listeriosis. This clearly illustrates that the mere presence of *L. monocytogenes* does not "cause the food to be unsafe for human consumption." We respectfully suggest that the Agency carefully consider this and the precedent regarding management of potential hazards such as *C. botulinum* as it attempts to develop regulations that are founded on science and are risk-based, in line with Agency intent to focus requirements and resources on products and processes that most require control for protection of public health.

Industry experience has shown that positive findings of *Listeria* spp. on food contact surfaces do not necessarily indicate the presence of *L. monocytogenes* on food contact surfaces or in product. Data presented by Dr. Martin Wiedmann on environmental *Listeria* testing at the FSIS technical conference in May showed that there is wide variation in the percentage of *Listeria* spp. that are confirmed as *L. monocytogenes*: 5-81% in the 5 plants in the study. In another study that Cornell University is conducting in the RTE seafood industry, the percentage of *Listeria* spp.-positives from food contact surfaces in smoked seafood plants that were confirmed to be *L. monocytogenes* ranged from 0% to 50%. In fact, in product tests 0-25% of samples that were positive for Listeria spp. were also positive for *L. monocytogenes*.

We believe the proposed approach to be fundamentally flawed as a means for minimizing the risk of listeriosis. If establishments introduce a CCP for recontamination other than a post-packaging lethality step and on this basis reduce their environmental monitoring, there is significant potential to reduce rather than enhance public health. We fear this unintended consequence of the FSIS proposal has a high potential to occur based on the following:

1. The proposed rule would not require food contact surface testing in establishments that have identified *L. monocytogenes* as a hazard reasonably likely to occur and established one or more controls in their HACCP plans after the lethality treatment. On May 26, 1999, FSIS published in the *Federal Register* a document stating that the findings from testing a range of ready-to-eat products and information from the investigation of outbreaks of listeriosis could

affect an establishment's hazard analysis; establishments were required to reassess their HACCP plans for ready-to-eat products and address *L. monocytogenes* contamination in their HACCP plans if it was reasonably likely to occur. A number of plants conducted this reassessment and added controls in their HACCP plans; presumably these establishments would be exempt from the testing required in this proposal. They may, therefore, choose to not conduct environmental monitoring.

2. Some establishments argued, in response to the May 1999 notice, that they were unable to identify one or two CCPs that could effectively prevent *L. monocytogenes* contamination of their products. However, they demonstrated that *L. monocytogenes* was a hazard not reasonably likely to occur as the result of an effective environmental control and monitoring program. Stringent, multi-faceted control programs were developed in many plants; these "prerequisite programs" involved many control points, no one of which could be considered critical to control *L. monocytogenes*. Industry feels that this is the best approach to address recontamination of products with *L. monocytogenes* when in-package pasteurization is not possible. However, given this proposed requirement to test product contact surfaces for *Listeria* spp., and to hold and test product if there is a positive on a food contact surface, a number of establishments will elect to include a CCP for *L. monocytogenes* in their HACCP plan. (FSIS estimates that the number of large plants with such a CCP will increase from 50% to100% and the number of small plants will increase from 33% to 50%.) If these CCPs are only "pseudo-CCPs," i.e., they do not fully prevent *L. monocytogenes* contamination, they will have limited effect on reducing the risk of listeriosis.

3. If establishments do not specify a CCP, it is likely that environmental monitoring programs may be modified in ways that will make them less effective. Some establishments may elect to do the minimum level of food contact surface testing because of the need to hold and possibly test product. (Establishments will likely feel compelled to hold product any time a food contact surface is tested as a result of the regulation, and therefore would reduce testing to the minimum required level in order to reduce the associated costs, which will be high.) Establishments may also feel compelled to hold other products produced on other lines the day of testing because of the potential for the test results to be applied to these products. Thus the aggressive environmental testing programs that many establishments employ to effectively reduce *L. monocytogenes* contamination could be scaled back, with a likely negative impact on public health. This is a scenario made more likely by the fact that a large number of companies do not have enough physical space to hold the amount of product that would need to be held as a result of the testing requirement.

The costs for such hold and test programs will be very significant for industry; in fact, they are likely to discourage industry testing. Moreover, we believe that a hold and test program for all food contact surface tests would be unmanageable. In our industry survey 46 out of 75

respondents (61%) representing 115 plants indicated that they did not have the space to hold product.

FSIS estimates the cost of mandatory food contact surface testing by the industry to be $5.53 million. This includes $1.28 million for HACCP plan modification, $1.75 million for testing, and $2.5 million for production adjustments. HACCP plan modification to incorporate a CCP was estimated at $5000, regardless of size of the establishment or the number of HACCP plans. The $1.28 million estimate ($5000/establishment times 257 establishments), is for the number of large establishments the Agency estimates will add a CCP. In considering the cost for sampling, the Agency established a $35 per sample rate to include shipping and handling and estimated that 50,035 tests per year will be conducted. Production adjustments involve changes to the process or facility to comply with the proposed rule, including discontinuing production of certain RTE meat and poultry products. The Agency has ranked these adjustments from minor (least costly) to the most radical (most costly) needed to remedy an establishment's *L. monocytogenes* related control problem.

We believe FSIS significantly underestimated costs to implement mandatory *Listeria* testing. First, we believe that the Agency incorrectly assumes that all 257 large establishments that currently do not have a CCP for *L. monocytogenes* will incorporate one. Second, we believe that the Agency's estimate of $5000 for incorporating a CCP grossly underestimates the cost. Although the Agency included lethality steps among its potential CCPs, clearly the Agency did not fully consider the potential company actions. We believe that some companies, primarily large establishments, will seriously consider incorporating in-package treatments such as pasteurization, high pressure processing (HPP) and irradiation to control *L. monocytogenes* in their products and would add a CCP to their HACCP plans. The costs for such processes are substantial. Although the capital equipment costs for post-packaging heat treatments are less than for HPP or irradiation, there will be significant research and development costs to develop formulations that meet consumers' expectations for quality. Costs for installation of HPP can be estimated in the range of $1 million per unit, and the limited volume each unit can handle would necessitate multiple units for establishments that produce high volumes of RTE products. Costs for an x-ray unit, which can handle much larger volumes of product, are significantly higher - $5-7 million. However, though approval of irradiation for RTE products is eagerly anticipated, the fact that FDA has not yet approved it is a possible explanation for the Agency not including this cost in its estimates.

Nevertheless, the most important costs FSIS did not address were the costs of holding product until sample results are obtained. The Agency did seek information on the need for additional storage to hold product when sampling occurs at the level outlined in the proposal. An industry survey identified 61% of respondents (and 71% of the plants producing RTE but not canned products) would incur costs for additional storage.

Costs, other than for testing, associated with holding product while awaiting test results include:

- Transportation costs
- Handling costs
- Storage costs
- Surplus inventory costs
- Distressed product costs
- Production destruction costs (In many cases product associated with positive test results will be destroyed whether it contains *Listeria* spp. or *L. monocytogenes*.)

In our survey, there was confusion about the type of information requested in relation to hold and test costs. The responses from some were clearly erroneous (e.g., numbers that resulted in a calculated 6 lbs of product per line). Others submitted information in varying formats. Wide variation in submitted costs for the above factors results in a wide range of estimated costs for hold and test programs. Some respondents provided handling costs of $9.00-11.25 per pallet and storage costs of $6.75-$9.00 per pallet. Another respondent indicated handling and storage costs of $15/day per pallet, and a third $10.70 per pallet. At least one respondent indicated that the estimated storage and handling charges did not include the charge for printing a bill of lading (an additional $2.50). One respondent provided shipping charges for shipments within a 500-mile radius of approximately $90-165 per pallet. Production estimates also varied widely. Based on some of the figures provided, we calculate hold and test costs as follows:

Cost Estimates				
Lbs / Line / Day	18,000	50,000	100,000	150,000
# pallets/line/day @1000-1500 lbs	12-18	33-50	66-100	100-150
Handling/storage (@$18/pallet)	$216-324	$594-900	$1188-1800	$1800-2700
2lines	$432-648	$1188-1800	$2376-3600	$3600-5400
4 lines	$864-1296	$2376-3600	$4752-7200	$7200-10,800
6 lines	$1296-1944	$3564-5400	$7128-10,800	$10,800-16,200
Annual costs	**$5184-23,328**	**$14,256-64,800**	**$28,512-129,600**	**43,200-194,400**

However, other respondents indicated the costs would be much higher. One respondent (that produces over 1 billion lbs of RTE product a year) indicated that the requirement for 4 tests per month would result in $17.8 million in annual costs (including transportation, handling, storage and costs to carry extra inventory). This did not include the $7 million cost incurred for distressed inventory. Another company that produces 728 million lbs of RTE product per year

estimated that to hold one day's production (over 2000 pallets of product), the cost would be $90,000-$121,000 for storage and handling. Assuming this occurs only once per month, their costs would be $1.08 million-$1.45 million annually. Yet another company has indicated that a hold and test program would cost them $30 million per year. If we were to assume that 100 of the 257 large plants that do not have a CCP for *L. monocytogenes* would implement a hold and test program, and we were to further assume that their costs are only $1 million for the program, we can see that costs for the large plants alone exceed $100 million.

As we have noted previously, we believe that *L. monocytogenes* control measures should differ based on the risk posed by the product. This includes environmental monitoring programs. Furthermore, environmental monitoring programs should be tailored to the specific establishment with respect to sites tested, frequency of testing, and actions taken in response to a positive. The finding of *Listeria* spp. may suggest the potential for *L. monocytogenes* to be present, however, as indicated by our earlier comment on finding *Listeria* spp. versus *L. monocytogenes*, clearly other *Listeria* spp. such as *L. innocua* are more common.

Moreover, since *L. monocytogenes* is so ubiquitous, sporadic contamination of the environment, including food contact surfaces, may occur but have little or no impact on product. The real problem occurs when *L. monocytogenes* finds a niche in the plant and results in ongoing contamination of product. It is only through aggressive testing of the environment that such harborage sites can be discovered and eliminated. Thus we do not feel it would be appropriate to require product testing based on a single positive *Listeria* spp. on a food contact surface. Investigation of <u>any</u> positive on a food contact surface should be done, and additional testing, that may include product testing, would be warranted for additional positives on the same surface or in the same area. However, since food contact surface positives are frequently isolated incidents, it would be a waste of resources to test product every time there is a positive on a food contact surface when those resources could be better spent on identifying real problems. It is the finding of repetitive positives (two or three consecutive findings of *Listeria* spp.) that indicates a potential harborage and warrants more in-depth analysis and product testing.

We suggest the following approach based on the scientifically sound risk assessment conducted by FDA and FSIS:

We believe that food safety is best promoted by a regulatory policy that encourages, rather than discourages, firms to 1) design products that inhibit the growth of *L. monocytogenes* and 2) test for, find and eliminate harborages for this ubiquitous pathogen.

***Listeria* testing provisions should be product type specific.** For example, for a refrigerated RTE product that supports growth, product testing may be appropriate based upon repeated positive environmental findings after corrective actions have been taken. However, provided

that an establishment has implemented a *Listeria* control program, we see no public health benefit to expending resources on product testing of the following:

- Products given a lethal treatment in the final package;
- Products in which growth of *L. monocytogenes* is controlled;
- Products in which formulation results in *L. monocytogenes* death (e.g., high salt, low moisture);
- Products that are frozen and subsequently heated.

For such products, the environmental monitoring program should specify actions such as enhanced sanitation to address the finding of *Listeria* spp. on a food contact surface.

If FSIS proceeds to mandate food contact surface testing, we urge the Agency to include in the final rule an option that provides incentive for and recognizes the efforts of firms that do more than minimal testing. The focus should be on devising a sampling scheme that is scientifically appropriate for specific types of products. We recommend a regulatory provision for an alternative to mandatory testing, as provided (at least in concept) for lethality and stabilization performance standards. If a firm has a prerequisite program and does more environment and food contact surface testing than the minimum and has a plan to address positives (e.g., root cause analysis and corrective actions), then it need not test product for *L. monocytogenes* on the basis of a single positive test result from a food contact surface.

We believe the Agency should provide an incentive for firms to reformulate their RTE products to retard the growth of *L. monocytogenes* and thereby minimize the risk their products would present in the marketplace. Products that are reformulated to prevent or retard growth, should not have to be tested. As previously stated the Agency should focus its resources and set industry requirements for those products that clearly present more risk.

We disagree with the Agency expectation that thermal processing firms will rewrite their hazard analyses to show *L. monocytogenes* as a hazard reasonably likely to occur. Thermal processes are designed for the destruction of organisms much more heat resistant than *L. monocytogenes*. Therefore, it is scientifically invalid to suggest that this organism "may cause the [canned] food to be unsafe for human consumption." The Agency suggestion that processors of thermally processed, commercially sterile products should identify *L. monocytogenes* as a hazard reasonably likely to occur in their hazard analysis would amount to a paperwork exercise, increasing cost to consumers and confusion among processors with no benefit to public health.

Performance Standards for Thermally Processed, Commercially Sterile Products

NFPA vigorously objects to the Agency proposal to replace the existing comprehensive canning regulations with abbreviated performance standards for thermally processed, commercially sterile foods and urges the Agency to withdraw this portion of its February 27 proposal. While we are generally supportive of appropriately designed and achievable performance standards, we believe the severity of the hazard addressed by the existing canning regulations along with other reasons discussed below justify their continuance in lieu of performance standards. During discussion of this issue at an FSIS public meeting on May 10, NFPA presented the industry case for leaving in the *Code of Federal Regulations* the existing regulations, which have been remarkably successful over recent decades in preventing consumer illnesses from canned foods. The unanimity of presentations by industry representatives, including a former government employee intimately familiar with the history of the canning regulations, represented a noteworthy consensus of opinion that the existing regulations are working and should not be voided, especially in the absence of any scientific justification for doing so.

Portions of our May 10 presentation are summarized below, followed by comments on several specific provisions of the proposal. A brief review of the development of federal regulations for low-acid canned foods is informative to this issue.

The canning regulations have had the strong support of the canning industry for nearly 30 years. Following a food poisoning incident in 1971 in which the failure to properly thermally process commercially canned product led to fatal consequences, the National Canners Association (now NFPA) petitioned the Food and Drug Administration (FDA) to publish new regulations to address the problem. The elements of a major new program were designed to control the primary food safety hazard associated with canning operations - the survival of spores of *Clostridium botulinum*, which could then germinate and produce the deadly botulism toxin in the anaerobic environment of the sealed can. Consumption of even small amounts of this potent toxin, in the absence of prompt administration of antitoxin, can quickly lead to paralysis and death of any consumer, not just those who might be immunocompromised or otherwise subject to special risk.

Experts from the NCA and its member companies identified the various steps in the canning process whose proper performance was essential to the manufacture of safe product. In cooperative effort with FDA, the most important features of various retorting systems, the essentials of thermal process establishment by recognized processing authorities and specific parameters of container closure were identified as mandatory requirements. Monitoring and record keeping requirements to document that factors critical to the thermal process were met, and prescribed procedures for corrective action when process deviations occurred, were also required elements of the regulation. In addition, advisory or recommended practices intended to

assure compliance with the required features were included. This strategy allowed industry flexibility to achieve a desired goal by alternative approaches most suitable for individual operations.

Along with new emergency permit requirements that provided FDA with a basis for enforcement, Good Manufacturing Practice (GMP) regulations applicable to "Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers" were published and made effective in January 1973.

Following several food poisoning incidents and one death from commercially canned meat and poultry products in the early 1970s, FSIS proposed a canning regulation in 1976, but it was never finalized. In September of 1981, NFPA petitioned FSIS to abandon its earlier proposal and to establish specific good manufacturing practice regulations that prescribe "detailed thermal processing requirements" for canned meat and poultry products.

On April 12, 1984, FSIS, noting its "... desire to provide maximum consumer protection by the most efficient means possible...", published a proposed rule in response to the NFPA petition. The option to develop comprehensive canning regulations "... was selected because it would accommodate advanced technology and would strengthen controls over canning operations to the degree deemed necessary to provide increased assurance of the safety and stability of canned product. Also, the development or [sic] regulations which are modeled after the proposed Codex Alimentarius Code of Hygienic Practice for canned foods, and which closely parallel existing FDA regulations, would serve to promote standardization and uniformity in national and international regulations." The preamble to the proposal also noted that the "... requirements and recommendations to be included in this proposal are generally recognized by the industry as essential to good canning operations and have been widely adopted."

FSIS published its final rule for canning establishments in December of 1986, and it became effective six months later. It is appropriate to emphasize that the FDA and FSIS canning regulations developed in cooperation with the canning industry have very effectively controlled the targeted serious public health concern - *C. botulinum*. Indeed, these HACCP-based regulations are widely regarded as the first and perhaps the most successful application to date of the principles of HACCP. The FSIS proposal to remove from the *Code of Federal Regulations* these industry-supported regulations and to replace them with abbreviated performance standards seems to overlook this unique background.

Our objections to the overall thrust of this portion of the FSIS proposal are numerous. In the preamble to the rule, **FSIS cites no public health basis for the proposed change.** This is not surprising since, by any measure of the effectiveness of regulatory food safety provisions, the existing regulations have been exceptionally effective in minimizing public health problems associated with canned foods. While new approaches for enhancing food safety may be

appropriate for certain foods, we do not believe the proposed changes to the canned food segment of the meat and poultry industry will yield any public health benefit. In fact, we fear that the proposed changes could have unanticipated and undesirable public health consequences that would adversely impact the very envious safety record of this segment of the food industry.

The proposed changes appear to be very likely to require **significant economic expenditures for validation of thermal processes** that are already exceedingly conservative and whose adequacy has been validated by many, many years of production of safe products. While the level of detail expected by the Agency regarding validation of lethality requirements for public health and for commercial sterility is not clear and must be clarified if the Agency should decide to proceed with its proposal, the potential costs to industry could be substantial. Yet, no public health benefit would accrue from such expenditures.

We note that in the cost analysis attached to the proposal, the Agency judged that canning facilities would incur no costs for implementation of the provisions of the rule. However, results of an industry survey indicated that the costs to validate the performance standard range from $75,000 to $4.8 million for the canning establishments that responded to the survey. While this provides only limited information, it suggests that the FSIS zero cost estimate overlooks certain major costs that would arise from these burdensome requirements that will not enhance public health.

Thermally processed commercially sterile products, which are heat processed to destroy all pathogens of concern and protected from post-process contamination by a hermetic seal, are so different from most other RTE products covered by this proposal that attempting to address all RTE products in a single rulemaking significantly complicates the total package. The overall proposed rule is rendered more difficult to follow by the need to repetitively exclude canning (there are six exceptions for thermally processed, commercially sterile products in the two columns of the *Federal Register* that address lethality and stabilization performance standards) from proposed provisions that are irrelevant to canned products.

The primary justification for the proposed change is to make the requirements for this industry segment consistent with those for other meat and poultry products. Overlooked is the fact that the change would create great disharmony with the requirements of FDA and with the recommended code of practice of the Codex Alimentarius Commission. As previously noted, uniformity of national and international requirements was one of the reasons FSIS published the rule in the first place. This is a significant issue that would introduce unnecessary complications for our members who produce FDA-regulated canned foods in addition to canned meat and poultry products and/or who export meat and poultry products to other countries. The proposed change would nullify the many years of effort aimed at achieving consistent regulations between the Agencies, despite the fact that the basic requirements for the production of safe canned foods are the same regardless of regulatory jurisdiction.

Another stated justification for the proposed change is to provide greater flexibility for industry to produce safe product in the most efficient manner. While the original FSIS canning regulations were somewhat restrictive, over the past 15 years many changes have been made, both at the request of industry and on the Agency's own volition, to eliminate unnecessary requirements, such as those for prior approval of alternative procedures that can be demonstrated scientifically to achieve the same end result. Indeed, the Agency has eliminated the many requirements in the original rule for mandatory prior approval of partial quality control (PQC) programs. After much effort, regulatory alternatives to the costly and HACCP-incompatible requirement for 10-day incubation of canned products are available. While a few additional changes along this line could be made, these can be accomplished easily with minor amendment of the existing regulations. The action proposed by the Agency is certainly not required to achieve this goal.

Upon review of the Agency's proposed version of guidelines for industry, we find that the sole change is the conversion of all required "shalls" to recommended "shoulds." We objected in the 1980's when the initial FSIS proposed rule converted many of the FDA's recommendations to requirements. We are also concerned about this current proposal to make all of the mandatory provisions advisory. As guidelines, the recommendations would not be suitable for regulatory enforcement or for compliance purposes. Processors, especially new ones or very small ones, would have no basis for knowing which of the requirements are of essential importance and which are merely examples of acceptable practices. Such a situation would seem to us to invite problems. On the other hand, if inspection personnel found fault with a processor's procedures that did not follow all of the recommended guidelines, then industry could rightfully argue that the Agency was attempting to enforce a guideline, a practice to which we have frequently objected in the past. We believe that years of experience have shown that the mix of mandatory practices and advisory recommendations in the existing canning regulations are on target and need not be changed.

We strongly object to the elimination of the regulatory recognition of the process authority. Elimination of the codified provisions for process development by processing authorities would increase the possibility that inadequate processes or procedures would be employed, especially by new and/or small processors. As processing systems become more complex and consumer demand for freshness and improved nutrient retention increase, recognized expertise in the development of thermal process schedules will become even more critical. In the face of these needs, diminished recognition of the role of processing authorities clearly could have an adverse effect of food safety. We also fear that elimination of regulatory recognition of the process authority concept could lead to an overall lessening of emphasis in this area to the eventual detriment of this industry segment. Indeed, adverse consequences for public health could arise if the elimination of these clearly understandable rules should lead any firm on its own volition to institute a questionable practice, which would readily have been recognized by a processing authority as unsafe. It is worthy to note that the development of valid thermal processes involves

much more than understanding the thermal inactivation kinetics for a particular product. For example, heat penetration rate, viscosity changes, amount of headspace, process variability and other factors can all be important in the development of safe processes. A thorough understanding of these matters is gained only through practical experience. The fine points of thermal process development and delivery are frequently not readily apparent to those without substantial experience in the field. The thermal process authority provides the requisite expertise to recommend sound processes and procedures that will protect the public health. By doing away with the regulatory significance of the process authority, it will be left to individual establishments to document that they meet the conditions of 12D for public health, as well as conditions for commercial sterility.

We disagree with FSIS setting a specific performance standard for minimum health purposes. The 12-D concept for assuring the elimination of spores of *C. botulinum* has never been codified by any Federal, state or international organization. The origin of the specific value is discussed in the preamble to the proposed rule. The state of the science of canning in the 1920's (regarding knowledge of microorganisms, capabilities of processing equipment and ability to deliver a precise process) justified very conservative assumptions that may not be warranted under some circumstances today. This high level of conservatism allows the safe use of general minimum health values that have proven their adequacy over many decades of use.

The lethality requirements for commercial sterility almost always significantly exceed 12D because of the need to destroy spores of more heat resistant spoilage organisms. Thus, the minimum health values are rarely utilized, other than in process deviation situations. Even then, it may not be necessary to know the 12D value if, as is frequently the case, the product can be reworked or reprocessed. Consequently, we view the FSIS proposal to require validation of 12D values for the host of meat and poultry products to be burdensome and unnecessary.

The original data establishing the common commercial sterility value that has been used for many years for thousands of processes for most meat/poultry products may not be easily found. The long history of safe use of these processes suggests that there is no pressing need to mount a major effort to uncover that work or to try to reproduce it. Most of the product-specific sterility values developed by individual companies, suppliers or other processing authorities are proprietary.

The extent of processes intended to be covered by this proposed section is not clear. The title of proposed § 430.5 "Thermally processed, commercially sterile products," would seem to limit its provisions to heat processed commercially sterile products; however, § 430.5(a) includes "other sporicidal lethality processing," which seems to expand coverage beyond heat processed products. If processes other than heat processing are intended to be covered, it seems odd and inappropriate that operators of such systems would have to complete a school of instruction for supervisors of canning operations. In any event, if the Agency were to proceed with

development of this rule, we would need assurance from the Agency that the use of systems and processes, other than canning, for improving the safety of meat and poultry products will in no manner be restricted or impeded.

As noted before, NFPA urges the Agency to withdraw from its proposed rule the proposed § 9 CFR 430.5 dealing with thermally processed, commercially sterile products. At a later date and under a separate docket, the Agency could undertake refinement of the existing regulations, while retaining their essential provisions. Certainly the Agency could combine and recodify the currently separate requirements for meat and poultry into a single section of the *Code of Federal Regulations*. Other modifications to eliminate any lingering restrictive requirements, along the lines of a document we shared with the Agency in 1997, could also be considered at that time. We are currently in the process of reviewing those prior recommendations to assure they are relevant to the current regulatory environment. As we have amply demonstrated over the past 20 years, we are more than willing to work with the Agency to assure the continued safety the products of this food industry segment.

Labeling requirements

We disagree with the proposed requirement for "refrigerate after opening" labeling for shelf-stable products. We are aware of only one instance in which failure to refrigerate a shelf stable product after opening has been a problem (a #10 can of cheese sauce); there have been no such problems with meat and poultry products. We understand that there are already products in the marketplace that bear this type of labeling. Despite the very limited food safety problems with these products, manufacturers who deem it useful to consumers are already providing this information.

We note that many shelf-stable, commercially sterile products are available in single serve containers; mandatory refrigeration labeling of such containers would create an industry burden, which unquestionably would provide no public health benefit. In lieu of mandatory labeling requirements that would impact only a small percentage of foods in the home, we suggest that consumer education efforts targeted at the importance of maintaining foods under refrigeration would reap the greatest benefits. This is due, in part, because such efforts could most effectively convey the need to refrigerate not only commercially manufactured products, but also, foods prepared in the home or taken home from restaurants.

Depending on the amount of lead-time provided to make the changes, the cost of compliance with these labeling requirements could be substantial. Data from the NFPA-AMI industry survey indicated the cost of the proposed "refrigerate after opening" labeling requirement to range from $0-72,000.

FSIS requested comment on the FDA guidance statements and their appropriateness for RTE meat and poultry products that are not shelf stable. We particularly would object to a mandatory requirement to apply the FDA-version of the NFPA/AFDO labeling recommendations to all canned products as it could create unwarranted concern for consumers initially, and if applied indiscriminately to all shelf stable products, could eventually be ignored by consumers. Mandated standardized wording would place an unnecessary burden on the industry when there is little evidence to suggest that consumers read every word on the label.

We appreciate the opportunity to provide input on these very important issues.

Respectfully submitted,

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